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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,724	03/26/2007	Victor Anomah Ngu	133059-01US	2192

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
05/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,724	NGU, VICTOR ANOMAH	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-9,11,13-20 and 30-36* is/are pending in the application.

4a) Of the above claim(s) *35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9, 11, 13-20 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 1/26/2009. The status of the claims is as follows: claims 1-6, 10, 12 and 21-29 are cancelled, claims 7-9, 11, 13-20 and 30-36 are pending, claims 7-9, 11, 13-20 and 30-34 under current examination and claims 35-36 are drawn to non-elected inventions.

Any objection or rejection not reiterated herein has been withdrawn.

Information Disclosure Statement

No IDS has been submitted for consideration.

Specification-MAINTAINED

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title "Vaccine and Method of use is nebulous".

Claim Objections-MAINTAINED

Claim 13 is objected to because of the following informalities: for the use of a random period; see lines 6, p. 3. Appropriate correction is required.

Claim 16 is objected to because of the following informalities: for the use of excessive commas in ",the," (line 3). Appropriate correction is required.

Claim Rejections - 35 USC § 103-MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9, 11, 17-20 and 30-34 remained rejected under 35 U.S.C. 103(a) as being unpatentable over Ngu (Journal of the Cameroon Academy of Sciences, 2001) in further view of Franks (Eur J Parm Biopharm, 1998) for reasons of record as set forth in action mailed 9/22/2008.

Response to Arguments

Applicant's arguments filed 1/26/2009 have been fully considered but they are not persuasive. Applicants amended the claims to include the following limitation: "diluting said biological fluid and diluting said aqueous extract in order to obtain antigens from approximately 100-200 viral particles per ml" (claim 13). Applicant contends that the dilution step is not taught or suggested in the prior art and would not be readily apparent to one skilled in the art (Remarks, p. 8).

In response, this limitation fails to overcome obviousness to one of ordinary skill in the art such that the ordinary artisan would have diluted the solution in order to optimize the concentration of experimental viral particles. It would be expected that obtaining antigens from a higher concentration of viral particles in solution leads to higher yields. Such adjustment is considered a result effective parameter. Note that serial dilutions are a widely taught and commonly known method in the art. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical; see MPEP 2144.05. Applicants fail to show that 100-200 viral particles per ml is a critical concentration range.

Separately, Applicant amended claim 17 to include the following limitation: "said person or said second animal being selected from the same population as said first person or said first animal" (claim 17). It would have been obvious for ordinary artisan to treat leukocytes of one person with antigens from another person of the same population or geographical region for a gain of convenience, including saving on shipping costs and using antigens which are nearby and readily accessible.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Claim Rejections - 35 USC § 103-NECESSITATED BY AMENDMENTS

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ngu (Journal of the Cameroon Academy of Sciences, 2001) in further view of Franks (Eur J Parm Biopharm, 1998) as necessitated by claim amendments.

Ngu describes making a therapeutic composition against HIV from blood isolated from patients concerned (HIV infected) and either ether or chloroform was used in order to destroy the viral envelope. The solvent is removed and the residue constitutes the vaccine comprising only the HIV antigens (column 1, page 5). While the reference does not describe an aqueous phase and a lipid phase following treatment of a lipid-extracting solvent, this is an expected result given the author performed the same steps, using the same materials. Using the isolated HIV antigens, the author then treated

leukocytes *in vitro* isolated from the person concerned and the treated cells were re-injected back into the patient. Purification of the leukocytes is described on pages 5 and 7 and the author claims that all traces of the serum were removed.

Ngu does not teach diluting said biological fluid and diluting said aqueous extract in order to obtain antigens from approximately 100-200 viral particles per ml (see claim 13).

This limitation fails to overcome obviousness to one of ordinary skill in the art such that the ordinary artisan would have diluted the solution in order to optimize the concentration of experimental viral particles. It would be expected that obtaining viral antigens from a higher concentration of viral particles in solution leads to higher yields. Such adjustment is considered a result effective parameter and serial dilutions are a widely taught and commonly known method in the art. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical; see MPEP 2144.05. Applicants fail to show that 100-200 viral particles per ml is a critical concentration range. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to adjust various parameters, including via dilution of the biological fluid and aqueous extract, in combination with the method steps taught by Ngu because dilution of viral particles would affect the antigen yields.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646